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EXAMINER	
SKELDING, ZACHARY S	
ART UNIT	PAPER NUMBER
1644	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/676,045	ILAN ET AL.	
	Examiner	Art Unit	
	ZACHARY SKELDING	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-13,15-20,23-46,50-63,66-72,83-126 and 143-166* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,6-13,15,19,24,30-32,144-151,165 and 166* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 1,5,16-18,20,23,25-29,33-46,50-63,66-72,83-126,143 and 152-164.

DETAILED ACTION

1. Applicant's amendment filed March 9, 2009 is acknowledged.

   Claim 11 has been amended.

   Claims 4, 14, 21, 22, 47-49, 64, 65, 73-82 and 127-142 have been canceled.

   Claims 1-3, 5-13, 15-20, 23-46, 50-63, 66-72, 83-126 and 143-166 are pending.

   Claims 2, 3, 6-13, 15, 19, 24, 30-32, 144-151, 165 and 166 are under consideration as they recite a method for the treatment of immune-related or immune-mediated disorders or diseases in a mammalian subject in need of such treatment, by manipulating the NKT cell population of said subject, wherein manipulation of said NKT cell population results in modulation of the Th1/Th2 cell balance toward anti-inflammatory cytokine producing cells, said modulation being mediated by different components, cells, tissues or organs of said subject's or another subject's immune system comprising various steps wherein the species of "immune-related or immune-mediated disorders or diseases" is "autoimmune liver disease" or "Crohn's disease"; the species of "culture conditions for the ex vivo education of NKT" includes "allogeneic antigens obtained from donors suffering from said immune-related or immune-mediated disease", "Kupffer cells" and "IL4".

   Claims 1, 5, 16-18, 20, 23, 25-29, 33-46, 50-63, 66-72, 83-126, 143, 152-164 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group and/or species of invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on March 10, 2008.

2. This Office Action is in response to applicant's amendment filed March 9, 2009.

   The previous rejections of record can be found in the Office Action mailed September 9, 2008.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

   The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 2, 3, 6-13, 15, 19, 24, 30-32, 144-151, 165 and 166 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for the treatment of TNBS-induced-colitis in a first mouse in need of such treatment comprising: (1) orally administering to said first mouse colitis extracted proteins (CEP) prepared from colons that were removed from TNBS-induced-colitis mice, cut into small strips, mechanically

homogenized, filtrated through a 40 mm nylon cell strainer, and the colitis extract supernatant separated from intact cells via centrifugation; (2) obtaining 0.5 x 10^6 liver associated lymphocytes and 2.5 x 10^6 splenocytes from a second mouse that had been treated with TNBS to induce colitis and had been orally administered CEP prepared as in step (1); (3) adding to a culture of the 0.5 x 10^6 liver associated lymphocytes and 2.5 x 10^6 splenocytes from step (2) antigen presenting cells and CEP prepared as in step (1); (4) optionally adding to said culture IL4, IL10, TGFβ, IL18 or IL15, (5) administering the cultured cells of step (3) to the first mouse in need of such treatment to modulate the Th1/Th2 balance toward anti-inflammatory cytokine producing cells, resulting in an increase in the quantitative ratio between any one of IL4 and IL10 to IFNγ

does not reasonably provide enablement for

a method for the treatment of ***any*** immune-related or immune-mediated disorders or diseases in ***any*** mammalian subject in need of such treatment, by manipulating ***any or all*** NKT cell population(s) of said subject, wherein manipulation of said NKT cell population(s) results in modulation of the Th1/Th2 cell balance toward anti-inflammatory cytokine producing cells, said modulation being mediated by ***any*** components, cells, tissues or organs of said subject's or another subject's immune system, essentially for the reasons of record as put forth in the Office Action mailed September 9, 2008.

Applicant's arguments

Applicant argues the claimed invention is enabled because murine NK1.1 T cells educated ex vivo in the presence of murine colitis extracted protein (CEP) produce more IL-10 than control NK1.1 T cells (compare experimental Groups E''5 and E''2 in Table 6 of the instant specification) in the same way that murine NK1.1 T cells educated in vivo by feeding of CEP produce more IL-10 when isolated in vitro (experimental Group E''3 vs. E''2) (see remarks page 28, 2nd paragraph to page 29, 1st paragraph).

Based on this applicant asserts, "clearly, the results in Table 6 indicate that NKT cells which have been trained by either method are effective in ameliorating inflammatory markers and producing a shift in the Thl/Th2 balance. Consequently, one of skill in the art would recognize that when subsequent experiments are performed with *in vivo* training, these results would also be obtained by *ex vivo* training as well." (see remarks page 29, 1st paragraph).

Applicant further argues the breadth of the claimed invention is enabled because any unpredictability in the NKT art is addressed by the ability of the claimed method to work without knowledge of the specific antigen(s) responsible for educating the NKT cells and without knowledge of the specific NKT cell type(s) that can successfully be educated according to the claimed method and used for treating immune-related or immune-mediated disorders (see remarks paragraph bridging pages 29-30 to page 32, 1st paragraph).

Lastly, applicant appears to make some arguments about the use of orally administered antigen to treat disease, see remarks page 30, 2nd paragraph in particular.

Applicant's arguments have been considered, but have not been found convincing, essentially for the reasons of record as put forth in the Office Action mailed September 9, 2009.

Ex vivo Education

With respect to applicant's first argument concerning the only working example of "ex vivo" education in the absence of APC and sans feeding in the instant specification (Example 7 on pages 79-85), applicant argues "The exact value of the IFNγ/IL10 is not important so much as the directionality, i.e., is IFNγ>IL10 or is IL10>IFNγ?"

Applicant asserts this notion is supported by the conclusion of the instant specification that "As shown by Table 6, culturing NK1.1+ T cells in the presence of disease associated antigens (subgroup E"5) leads to cytokine patterns that is similar to that of tolerized cells as manifested by increase IL10 secretion." (applicant's emphasis, see remarks page 28-29 bridging paragraph).

Applicant's argument is not found convincing because while it is acknowledged that the instant specification emphasizes the increased IL-10 secretion of E''5 vs. E''2 it is unclear how "the exact value of the IFNγ/IL10 is not important" when this is the very measure of treatment success recited, e.g., in claim 6: "c. re-introducing to said subject the educated NKT cells obtained in step (b) which may modulate the Thl/Th2 cell balance toward anti-inflammatory cytokine producing cells, resulting in an increase in the quantitative ratio between any one of IL4 and IL10 to IFNγ." Moreover, the working examples of the instant specification other than Example 7 report the value of the IL4 and IL10 to IFNγ ratio consistent with the importance of this measure to understanding the pro- or anti-inflammatory nature of NKT cells (see, e.g., Figures 2, 3, 5, 9, 11 and claim 6).

Thus, the skilled artisan would see that the E''2 experimental conditions, which essentially amount to removing NKT cells from a TNBS treated mouse, give an IL-10/IFN-γ ratio of 52:1, while TNBS mice orally administered colitis extract protein (obtained by treating mice with TNBS and then harvesting the colon and preparing a protein extract according to the methods put forth in the instant specification) as in E''3 have an IL-10/IFN-γ ratio of 230:1. However, removing the oral CEP step, i.e., essentially practicing the method as recited in claim 6 on a TNBS mouse gives the smallest IL-10/IFN-γ ratio, around 10:1 (E"5). So, given that E"2 must be considered the baseline, i.e., essentially isolating NKT cells from a patient having an immune-related disorder and culturing them ex vivo for some time in BSA, the skilled artisan would not know how to practice the claimed method to produce NKT cells capable of having some beneficial effect on the patient to be treated.

The Educating Antigen

The instant claims encompass in their breadth ex vivo education of NKT cell with any antigen or epitope associated with an immune-related or immune-mediated disorder or disease to be treated (see, e.g., claims 7 and 9).

Applicant argues "the present invention does not require one either identify the particular component(s) or isolate the particular component(s) in the CEP that induced both in vivo and ex vivo training of the NKT cells. All that is required for the production of the appropriate effects is the presence of the antigen a sufficient amount in the material that is administered."

As put forth in the previous Office Action at page 11, 3rd-4th paragraphs, the enabled embodiment of applicant's invention involves the use of an educating antigen which is a mixture of proteins, nucleic acids, lipids and other cellular constituents including adherent microbial cells and colon epithelial cells ("colitis extracted protein").

However, neither the instant specification nor the art seem to recognize what particular biomolecular constituent of "colitis extracted protein" is sufficient to mediate its biological effects when administered orally or ex vivo as put forth in the previous Office Action at page 11, 3rd-4th paragraphs.

Given this uncertainty as to the active agent(s), the particular steps used to prepare the "colitis extracted protein" exemplified in the instant specification will determine the composition of this extract. For example, an extract prepared by collecting the fluid phase from colon cellular material will have a different composition from an extract prepared by treating colon cellular material with a mild detergent and collecting the soluble and/or insoluble fraction, which will have a different composition from an extract prepared by sonicating colon cellular material and collecting the soluble and/or insoluble fraction etc.

Moreover, without knowledge of what component of CEP is responsible for educating the cells ex vivo the skilled artisan would have little hope of reliably predicting if any particular disease can even be a source of epitope or antigen that can be used in the claimed method.

NKT cell genus vs. subtype, e.g., NK1.1+, CD56+

The instant claims encompass in their breadth methods of ex vivo educating either the genus of NKT cells or particular subtypes of NKT cells such as CD56+ or NK1.1+ NKT cells (see, e.g., claim 32 and page 43, 2nd paragraph).

Applicant argues "the NKT population as a whole was used in Example 7 for use in ex vivo education and in numerous other Examples where the properties of NKT cells on metabolic and immunological effects were observed. The present invention [does] not require knowledge of which particular subgroups of NKT cells may be responsible for these effects."

Applicant's argument is not found convincing because the instant specification provides a single example of obtaining NKT cells, in particular, NK1.1+ NKT cells, from a mouse and

ex vivo "educating" the NKT cells in the presence of "colitis extracted proteins" obtained from a mouse with TNBS induced colitis. While the skilled artisan would be quite uncertain about the ability of these ex vivo educated ***murine NK1.1+ T cells*** to modulate the Th1/Th2 cell balance toward anti-inflammatory cytokine producing cells, resulting in an increase in the quantitative ration of IL10 to IFNγ and thereby treat ***murine TNBS colitis*** for the reasons given above in connection with applicant's first argument, assuming arguendo that this weren't the case the skilled artisan would consider extending the claimed method to the ex vivo education of ***any or all human NKT cell(s)*** to treat ***any human immune-related disorders or diseases*** to be a highly unpredictable endeavor for the reasons put forth in the previous Office Action, namely that the differences between the biology of human and mice NKT cells as a whole far exceed the similarities. (see page 12, 5th paragraph to page 13, 1st paragraph).

Furthermore, with respect to the specific human NKT cell subtype which is CD56+ (as recited, e.g., in claim 32) applicant argues "The Examiner further cites Doherty where CD56 cells are described as Th1 producing cells. Office Action page 14. Applicants assert that Doherty is not applicable to Applicants presently claimed invention which recites a shift in the Th1/Th2 balance. As such, one of skill in the art would understand that prior to 'education' the NKT cells may possess a Th1>Th2 cell balance."

Applicant's argument is not found convincing because there is no a priori reason to believe that the claimed ex vivo education of the NKT cells, for example in claims 6 or 7, is anything more than one mechanism to activate NKT cells, and as taught by Doherty human CD56+ NKT cells produce pro-inflammatory Th1 type cytokines upon activation (see previous Office Action page 13-14).

Furthermore, with respect to the teachings of Kaneko, applicant agues "this paper is concerned with the influence of IL4 on induction of inflammation and remarks that effects from IL4 result through 'an autocrine fashion'. As such, there is no indication that, after induction, a rise in IL4 level derived from treatment of mice with in vivo or ex vivo educated NKT cells would necessarily augment symptoms which took place during induction. As noted by the Examiner, the Vα14 cells used in Kaneko et al., are in fact a particular subset. Thus, treatment of the entire population of NKT cells may have a different effect than treatment of the one particular subset used by Kaneko."

Applicant's argument is not found convincing because there seems to be no reason why IL-4 producing NKT cells which induce hepatitis by killing liver cells wouldn't perpetuate hepatitis by killing yet more liver cells. Furthermore, the examiner is unclear what is relevant about applicant's emphasis on IL-4 acting in "an autocrine fashion" to stimulate NKT cell cytotoxicity. Also, that Kaneko showed the Con-A activated Vα14 NKT cell subset (a.k.a. "NK1.1 NKT cells") over-produce IL-4 and induce hepatitis illustrates that applicant's exemplified ex vivo educated NK1.1 NKT cells can worsen some diseases. Moreover, applicant gives no reason to believe that "treatment of the entire population of NKT cells may have a different effect than treatment of the one particular subset used by

Kaneko." Arguments of counsel cannot take the place of factually supported objective evidence. See, e.g., *In re Huang*, 100 F.3d 135, 139-40, 40 USPQ2d 1685, 1689 (Fed. Cir. 1996); *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984). See MPEP § 2145.

Adhesion molecules

The instant claims encompass in their breadth methods including steps where various adhesion molecules are included in the ex vivo education step, such as LFA-1, ICAM-1 and E-selectin.

Applicant argues that the use of these adhesions in the claimed methods is enabled because the prior art cited in the previous Office Action is concerned with the role of adhesions in NKT cell trafficking to the liver and skin but the claimed methods are not restricted to the treatment of particular organs such as liver or skin.

Applicant's arguments have been considered and have been found convincing with respect to E-selectin.

However, with respect to LFA-1 and ICAM-1 applicant's arguments are not found convincing because according to the instant specification liver resident NK 1.1 NKT cells are involved in peripheral tolerance (see instant specification page 8 through page 9-10 bridging paragraph).

Thus, as stated in the previous Office Action at page 15, 1st and 2nd paragraphs, the skilled artisan would consider the addition of LFA-1 and ICAM-1 to be highly unpredictable in that exogenously added LFA-1 or ICAM-1 could antagonize the binding of ex vivo "educated" NKT cells with liver cells thereby preventing the administered NKT cells from getting to the liver to induce bystander suppression of auto-reactive CD4+ T cells (see Emoto et al., J Immunol. 1999 May 1;162(9):5094-8, in particular, Abstract and page 5097, last paragraph).

Methods further comprising orally administering components, cells, tissues and/or organs…

The instant claims include a method of ex vivo educating NKT cells and administering the educated cells to a patient "***further comprising the step*** of eliciting in said subject immune modulation of said immune-related or immune-mediated disorder or disease by ***administering to said subject components, cells, tissues and/or organs derived from any allogeneic donor suffering from said immune-related or immune-mediated disorder, xenogeneic sources, syngeneic sources, autologous sources, non-autologous sources, immunologically functional equivalents, or any combination thereof***, wherein said components, cells, tissues or organs are administered ***orally***. (see, e.g., claim 15)

Applicant argues Margalit et al. (Am J Gastroenterol. 2006 Mar;101(3):561-8) teaches some moderate success in treating Crohn's disease with orally administered autologous extract prepared from colon biopsies removed from patients receiving a colonoscopy. Applicant continues "It is apparent that the method did work but the success rate was not as high as would be desired. As discussed in another comment on this article (Hyun and Barrett. 2006 Am J Gastroenterol 101; 569-571), the original Margalit report represents preliminary results and 'Larger scale studies using variable dosages, modes, and durations of Ag delivery will be required to optimize oral tolerance therapy in IBD.)'" (see applicant's remarks page 30, 2nd paragraph, applicant's emphasis shown).

Applicant's argument has been considered but is not found convincing.

Applicant's argument appears to be based on the teachings of Margalit, Am J Gastroenterol. 2006 Mar;101(3):561-8 as well as Hyun and Barrett, 2006 Am J Gastroenterol 101; 569-571 and yet applicant has provided copies of the abstracts for these articles but not the articles themselves. Thus, the teachings of the reference as a whole cannot be properly evaluated.

Moreover, even if "Margalit et al. (Am J Gastroenterol. 2006 Mar;101(3):561-8) teaches some moderate success in treating Crohn's disease with orally administered autologous extract prepared from colon biopsies removed from patients receiving a colonoscopy" as asserted by applicant (noting that the Margalit Abstract supplied by applicant teaches "oral administration of Alequel™ is a safe method for treatment of…CD…***its efficacy needs to be proven***"(emphasis added)), this would not convincingly demonstrate that the disclosure of the instant specification enables the enormous breadth of the claimed invention as put forth four paragraphs above.

This is because the prior art teaches a number of large, rigorous and definitive clinical trials and failures of oral antigen immunotherapy as taught by Pozzilli and Wiendl (see the previous Office Action paragraph bridging pages 11-12). Thus, the field of oral antigen immunotherapy is at best highly unpredictable and at worst totally unsuccessful.

In conclusion, when Applicant's arguments and the evidence of the instant specification are taken as a whole and weighed against the evidence supporting the *prima facie* case of unpatentability, the instant claims, by a preponderance of evidence, remain unpatentable. See M.P.E.P. § 716.01(d).

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 2, 3, 6-13, 15, 19, 32, 144-151, 165 and 166 stand rejected under 35 U.S.C. 102(b) as being anticipated by Ilan Yaron (WO 02051986, cited on an IDS), essentially for the reasons of record as put forth in the Office Action mailed September 9, 2008.

Applicant argues "The presently amended claims are directed to the subject matter not described in the '986 application. The present specification teaches that that the use of both oral tolerance and ex vivo education is in fact counterproductive. As described above, the present specification indicates that NKT cells which have been trained by either method are effective in ameliorating inflammatory markers and producing a shift in the Th1/Th2 balance. The '986 application does not teach each and every limitation of the present claims. Withdrawal of the rejection is respectfully requested."

Applicant's arguments have been considered, but have not been found convincing, essentially for the reasons of record as put forth in the Office Action mailed September 9, 2008.

Applicant's arguments have not been found convincing because applicant appears to be arguing limitations not claimed in stating "the presently amended claims are directed to the subject matter not described in the '986 application." The only amendment in applicant's most recent remarks was to claim 11 and this amendment cannot be said to prevent anticipation of claim 11 or any other claim because the only thing that has been done is to eliminate four of the plural of alternatives recited in claim 11.

Moreover, in contrast to applicant's argument there are no apparent differences between the teachings of the present specification and the '986 application with respect to the use of both oral tolerance and/or ex vivo education.

Thus, Ilan Yaron continues to anticipate the instant claims.

It is noted that the teachings of Ilan Yaron pertaining to the claimed invention are no more or less enabling than the instant specification is enabling to the claimed invention.

Moreover, the standard for what constitutes proper enablement of a prior art reference for purposes of anticipation under 35 U.S.C. § 102 differs from the enablement standard under 35 U.S.C. § 112 in that section 112 provides that the specification must enable one skilled in the art to "use" the invention whereas section 102 makes no such requirement as to an anticipatory disclosure.

For example, in Rasmusson v. SmithKline Beecham Corp (413 F.3d 1318, 1325-26 (Fed. Cir. 2005)), the Court of Appeals for the Federal Circuit held that prior art European patent application, EP No. 285383 ("EP '383") was an enabled reference for purposes of anticipation even though, according to the United States Patent and Trademark Office, Board of Patent Appeals and Interferences, (1) there was no reasonable scientific basis for a person of ordinary skill in the art to conclude that the claimed method would be effective in treating

prostate cancer, and (2) EP '383 did not provide any proof that the claimed method would actually be effective in treating prostate cancer.

7. No claim is allowed.

8. **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

   A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZACHARY SKELDING whose telephone number is (571)272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.
   If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
   Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zachary Skelding
Patent Examiner

/Ram R. Shukla/
Supervisory Patent Examiner, Art Unit 1644